QC Pulse

How EQAS / Proficiency Testing results can be used to investigate the root cause of the errors occurring in the laboratory.

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Ask the Experts:

Q: I am interested in attending a course on Basics of Quality Control. Please let me know if there is a training program I could attend.

A: Bio-Rad offers online training courses on various subjects related to the field of quality control. These courses are very valuable for the Lab personnel. You will need to log in to www.qcnet.com. Under the QC education tab, you will be able to find the available courses.

Currently the on going courses are as listed below.

- Controlling Error Using Biological Variation
- Putting Total Error to Work in the Laboratory
- Assessing Current In-Use QC Protocols
- Basic Lessons in Laboratory Quality Control
- Preparations and Considerations for ISO - 15189

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EQAS / PT - a powerful tool for investigating the root cause of errors

External quality assessment programs are accepted around the world as invaluable tools used by laboratories to assess the performance of their test systems. When used in conjunction with daily quality control, these external programs can give laboratories added confidence in their patient test results.

Participation in EQAS / PT program is easy. Lab’s EQAS / PT Results are compared to other laboratories using the same methodologies, instruments and reagents and the lab performance is evaluated. This Evaluation may reflect unacceptable results at some point. The big issue is not about having an unacceptable result, but our response to an unacceptable result. It is these unacceptable results that actually help us find and fix our systems so that the error does not repeat. CLSI document GP 27 A2, Using Proficiency Testing to improve the Clinical Laboratory; Approved guideline-2nd Edition, provides a systematic approach to investigation of unacceptable results, classification of types of errors, education of laboratory personnel, Monitoring PT results over time & using PT to evaluate methods.

Selection of the appropriate EQAS / PT program is extremely critical. A lab should consider that the PT samples behave as patient samples and the peer group sizes are significant enough to provide statistically significant comparisons. Frequency of challenges, adequacy and utility of the reports are also points which should be considered. Generally the differentiating characteristics of the EQAS programs are:

- Matrix appropriate samples
- Educational content
- Technical support
- Customer service

It may be very helpful to base the selection of EQAS programs on these criterion. EQAS / PT samples should be treated exactly as the patient samples. The following practice is inappropriate:

- To run the calibration on the day of reporting EQAS sample if it is not a scheduled / required calibration.
- To repeat the EQAS samples where as the patient samples are tested only once.
- To have a specific analyst run the EQAS / PT sample

Only if EQAS samples are treated as patient samples, the results will help identify the correct situation in the lab and help find & fix the problems.
Having selected the ideal EQAS / PT program and handled it correctly, the next challenge is to deal with the unacceptable results. The reports provided by the EQAS / PT providers are valuable tools to identify the errors in the lab. Various PT / EQAS providers will have different ways of indicating the variability in results. It is important to use this information for purpose of investigation. Following are some of the examples to help analyze the EQAS / PT data.

**Investigating EQAS / PT performance**

The LJ graphs are an extremely useful indicator of your performance for the said analyte over past 12 months. This is a plot of your SDI (may be Z score or % error) values from the mean of comparator (Peer group mean).

Following are some of the examples how the LJ graphs could be used for purpose of investigation:

**Example 1 - All the sample results are on one side of the mean**

The following graph would indicate a bias in the results where all the samples are reading on the higher side.

**Ex. 1 - Levey-Jennings Chart: Uric Acid**

1. **The method codification may be incorrect.** Your lab results may not be compared to your peer group (same instrument – same method). It is important that your lab data is compared with the correct peer group for appropriate analysis.

2. **The system may not be calibrated as per requirement / recommendation.** If the calibration has shifted, all the recoveries will be either low or high depending on the calibration shift. Ideally the system should be calibrated as per the frequency as recommended by the manufacturer or in event of control failure. In such an event you may want to look at the performance of the daily controls. Most likely the daily controls would also show this shift. However, it is important when you look at the performance of the daily controls do compare the performance with the established mean or the peer group mean. Comparing the values with the pack insert mean may be misleading. Ideally a lab should establish its own mean and ranges for the daily controls. The control performance should be monitored against this established mean value.

**Example 2 - All the results by far are close to the mean however one shows sudden deviation**

There can be multiple causes of this kind of behavior

**Ex. 2 - Levey-Jennings Chart: Phosphate**

1. **Systemic error may have seeped in the system** anytime after the last EQAS sample reporting. In such a case it is best to go back and look at the daily controls. You should check if there is a deviation in the recovery of the control values. Do the control recoveries appear to have shifted? Bear in mind that it is possible that the control shift may not have been significant enough to cause a run rejection depending on the rules selected for purpose of control data analysis. EQAS data however offer a narrow window for errors.

2. **This may be a random error** - A sudden unexpected deviation. In this case it may be useful to keep a close watch on the performance of daily controls and the following EQAS sample results for this analyte.

3. **Was the appropriate sample tested?** May be the wrong sample was evaluated and the results submitted.

**Example 3 - Erratic results**

This pattern can be indicative of the following:

1. **This can indicate that the precision of the testing systems is poor.** You may look back at the daily controls and will see that the CV for this analyte may be higher than that expected. There can be various reasons for such imprecision.
The instrument – method system performance may not be good enough. You may want to look at all the possible sources contributing to poor precision such as sample handling/ sample preparation/ pipette calibration etc. It may also be good to look at the peer group data for this analyte and if the problem is particularly with your lab or with all the labs using this instrument –method. This will help you arrive at the root cause of the problem.

2. Alternately such a performance can be indicative of concentration related performance. You should check if the deviations are high at particular concentrations. In which case there may be issues with the detection at those particular concentrations and you may want to check with your reagent manufacturer.

Example 4 - Trends
Sometimes you may be see trends in the performance of EQAS data. You should in such a case be proactive and keep a close watch over the daily controls and see if there is a gradual increase / decrease in the controls recoveries.

Example 5 - Data submitted with the wrong units
Sometimes the units in which the data is being compared may be different form that you report. In which case if you have missed on converting the data to appropriate units, your data may appear as outlier.

Example 6 - Wrong Method codification
Sometimes your analyte may not be coded correctly. This will lead to your data being compared to inappropriate peer group and your results may reflect as outliers.

The above are just some examples and the reasons for unacceptable performance can be many. In general the sources of the errors can be broadly classified as follows:

- Clerical errors / Transcription error / Typographical errors
- Errors related to Method codification / method performance / procedural errors
- Errors related to equipment performance
- Technical problems/ Personnel related problems / sample handling
- Problem with the PT material
- Problem with PT evaluation / inappropriate peer group

EQAS / PT - corrective action and documentation of unacceptable results

Ideally laboratories should have written procedures to handle unacceptable result with respect to specific activities needed to detect, understand and correct the identified problems. Accreditation requirements specify several activities for responding to unacceptable results. These activities should include an assessment of the impact of the problem on patient test results, an investigation into the root cause of the problem, corrective action and subsequent auditing to verify that the corrective action has been effective.

EQAS / PT reports reflect the performance of the method instrument systems in the lab. If used in conjunction with daily controls EQAS / PT reports can serve as a valuable tool to investigate the root cause of the problems and thereby improve lab practices.

Regular participation in a proficiency-testing scheme provides independent verification of the analytical competence of a laboratory and shows a commitment to the maintenance and improvement of performance. It demonstrates to the public, customers, accreditation bodies, regulators, and management that analytical procedures are under control and gives analysts confidence that the service which they provide will withstand scrutiny.

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